A novel method and kit for targeted de novo bone repair; an "In vivo bone bioreactor".

**OCR Number**: OCR 1674

**Description:**
A collaborative research effort, performed in part with Yale, has identified a unique method to induce the formation of new bone in targeted skeletal sites, as well as accelerate and secure the repair process of fractures. This technology is osteoinductive and is best suited for bones at risk for fractures and their repair, such as the wrist (radius), hip, and spine. This method, which combines outpatient intervention and hormonal therapy, is a revolutionary new way to target locally de novo bone formation and maintain the new bone in place for a controlled duration. In vivo experiments have demonstrated the incorporation of calcein into mineralizing bone of the marrow cavity, following marrow aspiration and PTH treatment. Currently, there is no technology that exists to induce local bone formation except for bone morphogenetic proteins, which have restricted effects and limited bone induction. In addition to its ability to locally increase bone density in any bone to prevent fracture, this technology can also be applied to reconstructive surgery as well.

**Value Proposition:** Conventionally, to align and stabilize a bone after a fracture, an intramedullary rod is inserted into the bone marrow cavity for support and load-sharing. The approach utilized in this novel technology consists of aspirating the bone marrow to locally induce bone formation and then to simultaneously treat with parathyroid hormone (PTH). PTH has roles in the repair and regeneration of tissues, including bone, skin, and various organs and is already approved for the treatment of conditions such as osteoporosis. This aspiration/hormonal treatment combination has been shown to induce the formation of new bone and to extend the life span of the new bone that would otherwise be rapidly resorbed and replaced by bone marrow cells. Additionally, depending on the location of the fracture, this procedure may include pins to maintain bone parts together to allow patient mobility. The concept design is applicable to any bone and will be most efficient, if preceded by bone marrow aspiration and moreover can be performed immediately in patients who have sustained a fracture.

**Stage of Development**: Preclinical POC in small animal models.

**IP Status**: Use of parathyroid hormone (PTH) and calcitonin (CT) to induce and maintain new bone formation. Patents issued in the U.S. (7,531,518; 7,648,965; 7,648,700; 7,776,826) and Australia; ongoing patent prosecution in Canada, Europe, Japan, and China. OCR 4727: Method of bone augmentation (ongoing patent prosecution in the U.S. and Canada) OCR 4693: Methods and compositions for fostering and preserving bone growth (ongoing patent prosecution in Australia, Canada, Europe, Japan, and China).

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